

**CANNON BUILDING** 861 SILVER LAKE BLVD., SUITE 203 **DOVER, DELAWARE 19904-2467** 

STATE OF DELAWARE **BOARD OF PHARMACY** 

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PUBLIC MEETING NOTICE: **BOARD OF PHARMACY** 

DATE AND TIME: Wednesday, January 18, 2017 9:30 am

Conference Room A, 2<sup>nd</sup> Floor Cannon Building PLACE:

861 Silver Lake Blvd., Dover, DE 19904

APPROVED: February 15, 2017

# **MEMBERS PRESENT**

Susan Esposito, R.Ph., Professional Member, President Hooshang Shanehsaz, R.Ph., Professional Member, Vice President Kimberly Robbins, R.Ph., Professional Member Tejal Patel, PharmD, Professional Member Jay Galloway, Public Member Gayle MacAfee, Public Member

# **MEMBERS ABSENT**

Bonnie Wallner, R.Ph., Professional Member Julia Wheatley, Public Member Samantha Nettesheim, Pharmacist Administrator

# **DIVISION STAFF/DEPUTY ATTORNEY GENERAL PRESENT**

Eileen Kelly, Deputy Attorney General Christine Mast, Administrative Specialist III Michelle McCreary, Pharmacist Compliance Officer David Mangler, Director

#### **ALSO PRESENT**

David Medvedeff David Dryden **Deb Hamilton April Hourtford** Jerry Bliss Tim DeRose **Emily Sum** Jen Raubley Steve Shipper Marianna Koerner C Scott Kidner

**Brian Redding** Bill Vick

Erin Whaley

Michelle Crosier

Rachel Beaston

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# **CALL TO ORDER**

Ms. Esposito called the meeting to order at 9:31 a.m.

# **REVIEW OF MINUTES**

A motion was made by Mr. Shanehsaz and seconded by Ms. MacAfee to approve the meeting minutes for November 16, 2016 with corrections. The motion carried.

### **UNFINISHED BUSINESS**

A motion to amend the agenda to move #IV.E. MedsOnQue to the first item of unfinished business was made by Mr. Shanehsaz seconded by Ms. MacAfee. The motion unanimously carried.

<u>MedsOnQue</u> – Mr. David Medvedeff introduced himself to the Board. He provided a PowerPoint and video presentation which provided detailed information on the MedsOnQue product. The Board discussed changes to regulation 5.2.4 which states "written or printed information shall be included with the prescription" in certain circumstances. The Board discussed changes to the regulation to be inclusive of new technology such as MedsOnQue. A motion to approve the use of MedsOnQue so long as the requirements of regulation 5.2.4 are also met was made by Mr. Shanehsaz seconded by Ms. Robbins. The motion unanimously carried.

The Board also requested that review of regulation 5.2.4 be added to the legislative committee's agenda to make sure regulations are in place to support this technology.

### Statutory and Regulatory Discussion -

FDA Veterinary Compounding Regulation 5.1.7 – Ms. Kelly presented the Board draft regulation dated January 18, 2017 for review. To be published March 1<sup>st</sup> in the register of regulations with written comment period of 30 days to follow publication. A motion was made by Mr. Shanehsaz and seconded by Mr. Galloway to approve the draft legislation. The motion unanimously carried.

Freedom of Choice Proposed Regulation 3.10 – a motion to send this item back to the legislative committee for further review was made by Mr. Shanehsaz seconded by Ms. Patel. The motion unanimously carried.

Executive Order 60 Substantially Similar Crimes Listing Review – Ms. Kelly presented draft regulations changes for 17.0 for review. The Board reviewed the draft and requested that 17.2.63 of the draft be stricken. A motion to approve with the correction was made by Mr. Shanehsaz seconded by Ms. Robbins. The motion unanimously carried.

Telemedicine Pharmacy Regulations - a motion to table for further review with Ohio Board of Pharmacy was made by Mr. Shanehsaz and seconded by Ms. Robbins. The motion unanimously carried. The Board requested that this item remain on the agenda.

Outsourcing Facility Licensure – Ms. Kelly stated she is preparing draft regulation for review at the next meeting.

A motion to publish the following regulations changes March 1, 2017, Executive Order 60 Crimes Listing, The Veterinary Compounding Regulations, and Controlled Substance Continuing Education Requirements was made by Mr. Shanehsaz seconded by Ms. Patel. The motion unanimously carried.

Continuing Education Extension Review for Samantha Nettesheim – a motion to approve the submission of continuing education for the 2016 renewal was made by Mr. Shanehsaz seconded by Mr. Galloway. The motion unanimously carried.

#### PRESIDENT'S REPORT

Ms. Esposito provided the following report:

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I attended the Legislative Committee Meeting held on Friday December 16th.

DPS Health Awareness Programs: I am working with Jessica Spence and Liz Ryan on 3 Programs to be conducted in Sussex County at the Greenwood Library; February 24<sup>th</sup>, Heart 360 program, March 10<sup>th</sup>, Medication Adherence, March 24<sup>th</sup>, Diabetes Risk Assessment. There will be a number of incentives offered for each session with a larger gift pack offered to those attending all 3 sessions.

I attended the DPS General Membership Meeting Tuesday January 17th in Smyrna, DE.

I would like to announce the reappointment of a number of our Board Members by Governor Markell: Tejal Patel, Bonnie Waller, Hooshang Shanehsaz as well as myself.

I recently visited the newly renovated Acme Pharmacy in Rehoboth Beach, DE to compare the old facility with the newly constructed one. We discussed some of the programs they are now offering their patients including a new Diabetes program and gathered some of the concerns they identified related to patient information availability.

### **NEW BUSINESS**

Ms. Esposito read into the record the following ratifications: Pharmacist and Intern Licensure Approval Ratifications

#### Pharmacist:

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Shidie		Tang	A1-0005030
Danielle	Claire	Parmley	A1-0005031
Dianna	Naree	Kenner-Staves	A1-0005032
Nnamdi	F	Ofoegbu	A1-0005033
Elizabeth	E.	Austin	A1-0005034
Kassahun	Tsehay	Bogale	A1-0005035
Farooq	Adedey	Adetola	A1-0005036
Sarah	Elizabeth	Mangham	A1-0005037
Magued	M	Saad	A1-0005038
Marian	M.Y.	Morcous	A1-0005039
Hai	N	Nguyen	A1-0005040
Anthonia	Ο.	Eruchie	A1-0005041
Justin	Daniel	Miller	A1-0005042

#### **Pharmacist Intern:**

Katharine Anne Lawrence A7-0002443

A motion was made by Mr. Shanehsaz and seconded by Ms. Patel to approve the ratification of the Pharmacist/Intern applications. The motion unanimously carried.

Non-Resident Pharmacy Licensure Approval Ratifications

Premier Health Pharmacy, Inc.	A9-0001927
AllCare Specialty Pharmacy, LLC	A9-0001928
Medi Script Pharmacy	A9-0001929
Workers First Pharmacy Services, LLC	A9-0001930
Fresenius USA Manufacturing, Inc.	A9-0001931
PharmaScript Inc	A9-0001932
Choice Rx Pharmacy, Inc.	A9-0001933
Guardian Pharmacy	A9-0001934
Triad Isotopes, Inc.	A9-0001935
Triad Isotopes, Inc.	A9-0001936
Albertsons-Safeway Pharmacy #4705	A9-0001937
Walgreens #05823	A9-0001938
HYVACS, LLC dba Hy-Vee Pharmacy Solutions	A9-0001939
Jupiter Compounding LLC	A9-0001940
Wellpartner, Inc.	A9-0001941
A1Ability Pharmacy, Inc.	A9-0001942
Nutrition Plus Inc.	A9-0001943

A motion was made by Mr. Shanehsaz and seconded by Ms. Patel to approve the ratification of the Non Resident Pharmacy applications. The motion unanimously carried.

### Wholesale Distributor Licensure Approval Ratifications

Seacoast Medical, LLC	A4-0000883
HF Acquisition Co. LLC	A4-0001722
Healthsource Distributors, LLC	A4-0002363
Miller Veterinary Supply Co. Inc.	A4-0002364
RxTPL, LLC	A4-0002365
Westminster Pharmaceuticals, Inc.	A4-0002366
Nitrous Oxide Corp.	A4-0002367
TQM, LLC dba Two Rivers Medical	A4-0002369
Janssen Pharmaceuticals Inc.	A4-0002370
Solubiomix LLC	A4-0002371
Central Admixture Pharmacy Services, Inc.	A4-0002372
Lone Star Pharmaceuticals, Inc.	A4-0002374
Advanced Pharma, Inc.	A4-0002375

A motion was made by Mr. Shanehsaz and seconded by Ms. Patel to approve the ratification of the Wholesale Distributor applications. The motion unanimously carried.

### Medical Gas Dispensers

None

# Retail Pharmacy Licensure Approval Ratification

Concord Pharmacy A3-0001008

A motion was made by Mr. Shanehsaz and seconded by Ms. Patel to approve the ratification of the Retail Pharmacy application. The motion unanimously carried.

# Non-Retail Pharmacy Licensure Approval Ratification

The Poultry Pharmacy, LLC A8-0000006

A motion was made by Mr. Shanehsaz and seconded by Ms. Patel to approve the ratification of the Non-Retail Pharmacy application. The motion unanimously carried.

#### Outsourcing Facility

Advanced Pharma, Inc.	AD-0000036
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A motion was made by Mr. Shanehsaz and seconded by Ms. Patel to approve the ratification of the Outsourcing Facility applications. The motion carried.

# Pharmacist-In-Charge Interviews

A motion was made by Mr. Shanehsaz and seconded by Ms. Patel to amend the agenda to add the following for PIC interviews. The motion unanimously carried.

Ms. Robbins conducted PIC interviews with the following Pharmacists/Consultant Pharmacists in Charge: Pharmacist In Charge – Jerry Bliss, Option Care, Newark, DE.

A motion to amend the agenda to include the following was made by Mr. Shanehsaz seconded by Ms. Patel. The motion unanimously carried.

Pharmacist In Charge - Emily Sum, Acme #2682, Wilmington, DE

Pharmacist In Charge – Rachel Beaston, Acme #78116, Middletown, DE

Pharmacist In Charge – Marianna Koerner, CVS #10103, Newark, DE

Pharmacist In Charge – Alethia Medley, Rite Aid #11189. Dover, DE

## **Review of Consent Agreement**

Jay Patel, R.Ph. – a motion to approve the consent agreement was made by Mr. Shanehsaz and seconded by Ms. MacAfee. Ms. Esposito recused herself as the contact person. The motion carried.

# **Board Review of Facility Applications**

Olin Pharmaceuticals, LLC. (UT) - A motion to approve the application was made by Mr. Shanehsaz and seconded by Ms. Robbins. The motion unanimously carried.

Avella of Deer Valley, Inc. (AZ) - A motion to approve the application was made by Ms. Robbins and seconded by Mr. Galloway. The motion unanimously carried.

Tri-Coast Pharmacy, Inc. (FL) - A motion to propose to deny the application was made by Mr. Shanehsaz and seconded by Ms. Patel. The motion unanimously carried.

Emerson Pharmacy, Inc. (CA) - A motion to approve the application was made by Mr. Galloway and seconded by Mr. Shanehsaz. The motion unanimously carried.

Paragon Healthcare Specialty (TX) - A motion to approve the application was made by Ms. Robbins and seconded by Mr. Galloway. The motion unanimously carried.

### Pharmacist & Pharmacy - Discussion/Action Items

Dispensing of Naloxone – Jamie Mack, Division of Public Health – tabled until February 15, 2017 by the request of the presenter.

Pennsylvania PDMP, DE Practitioner Access – Ms. Esposito reported that you must be licensed practitioner in PA to be granted access to the PA PDMP.

## **COMMITTEE REPORTS**

**Legislative** – Jay Galloway, Kim Robbins, Tejal Patel, Hooshang Shanehsaz and Gayle MacAfee

Mr. Shanehsaz reported that the last committee meeting held December 9, 2016 was very productive and the committee addressed and discussed many of the agenda items. The completed items were on today's agenda for Board review. Outstanding items will continue to be discussed.

**Continuing Education** — Bonnie Wallner, Tejal Patel:

No Report

Consumer Affairs - Jay Galloway and Julia Wheatley

No Report

### Professional Liaisons - Kim Robbins, Tejal Patel and Hooshang Shanehsaz:

Ms. Esposito stated DPS will hold its annual convention in May 2017. There will be many continuing education opportunities available during the convention.

Controlled Substance Liaisons - Tejal Patel, Hooshang Shanehsaz, Jay Galloway:

No Report

## INSPECTION & PMP REPORT - Michelle McCreary, Samantha Nettesheim

Mr. Mangler reported that the current vendor for the Prescription Monitoring Program (PMP), Health Information Design (HID) has been sold to Appris. He will be meeting with Appris in the near future to discuss the changes that will occur from HID to Appris.

Ms. McCreary reported that she completed the following inspections:

- 6 Drug Take Back Kiosks located in Walgreens Pharmacies throughout the state
- 3 Remodel Inspections
- 1 Temporary Pharmacy Hospital Inspection
- 1 Pre-Construction Inspection
- 1 Opening Inspection
- 1 Closing Inspection

# **BOARD CORRESPONDENCE**

Ms. Esposito read the following correspondence,

National Association of State Controlled Substances Authorities - Resolution 2016-01

National Association of State Controlled Substances Authorities – Resolution 2016-02

National Association of State Controlled Substances Authorities - Resolution 2016-03

# **NEWSLETTER UPDATES**

None

### OTHER BUSINESS BEFORE THE BOARD

None

#### **PUBLIC COMMENT**

Mr. David Dryden stated that practitioner facility inspections could be completed if the practitioner's facility holds a controlled substance registration. This would allow for an inspection to occur to ensure that all statutory and regulatory requirements are being followed. He also stated that there is a provision under Title 16 Chapter 33 (01-19) under the Pure Food and Drug Act that allows the Board of Pharmacy or Office of Controlled Substance to complete an inspection under certain circumstances.

### **NEXT SCHEDULED MEETING**

The next meeting is scheduled for February 15, 2017 at 9:30 Am., 1st Floor Conference Room.

### **ADJOURNMENT**

There being no other business before the Board a motion to adjourn the meeting was made by Mr. Shanehsaz and seconded by Ms. Patel at 11:50 am. The motion unanimously carried.

Respectfully submitted,

Christine Mast Administrative Specialist III Liaison, Board of Pharmacy